A User Centered Approach to Eliciting and Representing Experience in Surgical Instrument Development

Restrepo-Giraldo, John Dairo; Nielsen, Teit Anton; Pedersen, Simon; McAloone, Timothy Charles

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J. Restrepo, T.A. Nielsen, S.M. Pedersen, T.C.McAloone
Department of Management Engineering, Technical University of Denmark
DTU Byg 404, DK-2800 kgs. Lyngby
{jdrg;tmca}@man.dtu.dk ; kandidate.medico@gmail.com

Abstract
Requirements elicitation for surgical equipment development is a challenging task. On the one hand, designers need to acquire a significant amount of domain and procedural knowledge to understand and discuss surgical tasks, which is difficult and resource intensive. On the other hand, there are restrictions to surgeons observation related to ethics, regulations and availability. This paper proposes a framework for the elicitation, representation and communication of surgeons' experience and their translation into requirements and concepts for new surgical instrument development. The framework is showcased by the development of an improved surgical instrument for laparoscopic surgery.

Keywords:
User Experience, User Centred Design, Surgical Task Analysis, Requirements Engineering

1 INTRODUCTION

The development of medical equipment and surgical instruments in particular, is characterised by a series of factors that make the process difficult and challenging. On the one hand, regulatory authorities impose stringent restrictions in terms of biocompatibility, robustness, reliability, repeatability of tests, suitability for the task or treatment, and documentation. On the other hand, design teams are often confronted with the need to process large amounts of *domain* and *procedural* knowledge to be able to understand, discuss and contribute to the development of new instruments or the improvement of existing ones. Moreover, the ability of a company to identify new opportunities is limited by the ability of the responsible team to understand the surgical procedures, the factors affecting the quality of the surgery, the safety of the patient and the safety of the surgeons.

A series of interviews with medical companies has revealed that current participatory design methods are insufficient to capture surgeons' experience, and are limited in their ability to support the identification of new areas for instrument improvement or new developments.

This paper reports on the results of those interviews, and proposes a framework to support the processes of capturing, representing and communicating surgeons' experience, requirements generation and translation into new concepts for new surgical instrument development.

The framework is constructed using knowledge classification theory [2][10],[11] and was built to map which observation- and data analysis techniques [8][1] are best suited to the specific type of knowledge being captured. Most methods proposed in the framework have been adapted to the restrictions of carrying out observation in an operating theatre, such as ethical considerations of video filming and difficulties in communicating with medical personnel during surgery.

The framework is showcased as an approach used for the development of an improved surgical instrument for laparoscopic surgery. The case study includes a validation cycle in which both the relevance of the requirements and the suitability of the concepts generated are tested with hospital surgeons. The paper concludes with a set of recommendations to companies on how best to use resources to capture and use surgeons' experience on the development of new surgical equipment.

2 INTRODUCTION TO THEORY AND METHODS

2.1 Requirements and Requirements Elicitation

Current requirements elicitation techniques such as those proposed by Beyer and Holtzblatt [1] are designed to be generic. These generic techniques are insufficient to elicit requirements in complex environments. Complex environments are characterized by:

- critical decision-making
- low tolerance for errors
- team collaboration required
- highly specialised knowledge required
- highly specialised skills required to operate
- possible unforeseeable events can have catastrophic consequences

Surgical environments can be considered complex environments, as they comply with the above characteristics. Additionally, eliciting requirements in these environments is challenging due to legal and ethical issues and the low availability of the stakeholders (i.e. surgeons) [6].

The term *elicitation* is preferred to the more common used term *requirements capture* as the latter implies requirements are readily available to be captured. In these environments, the knowledge and experience that is elicited needs to be interpreted, represented, communicated and validated to the design team and ultimately transformed into requirements, concepts and product features. The methods used for these elicitation processes are highly influenced by the type of knowledge being processed. In this paper, we deal with a process in which surgeons' experience is to be elicited in order to identify new opportunities for product improvement or for new concept development.

2.2 Current Participatory Design Methods and Requirement Elicitation Techniques

Elicitation methods vary greatly in their use of resources, level of detail and the kind of knowledge that needs to be captured. A classical distinction in elicitation methods considers them as classical methods (interviews, surveys and questionnaires), group methods (workshops and user panels), cognitive methods (protocol analysis, laddering, and cognitive walkthroughs), and contextual inquiry [11][1].

Efforts have been made to provide medical devices companies with good practices for requirements elicitation. Cysneiros [6] presents a series of recommendations on which methods to use or to avoid and how the use of these methods can be affected by the conditions of the medical environments. For instance, videoing can have legal, ethical and privacy-related consequences and protocol analysis can be inconvenient when doctors are attending acute situations. Alexander *et al* [5] present a framework for requirements elicitation and good practice and Jalote-Parmar *et al* [7] present a template based observation technique developed to elicit requirements for the development of information systems to support surgeons. However, none of these works address specifically the assessment of the relevance of the knowledge captured, the matching of elicitation methods to the type of knowledge to be elicited or the modelling or representing of this knowledge. This paper intends to contribute to these areas.

2.3 Knowledge Categories

Understanding and distinguishing the different types of knowledge from a user-environment is critical for the success of the elicitation process. Acknowledging the existence of explicit and tacit knowledge and the subdivision by Blackler's knowledge types is an important part of the elicitation process, but how this knowledge is integrated into actual methods is not entirely clear, nor easy.

The elicitation process can be optimised by structuring it with a view to handle knowledge gathering in accordance to Nonaka's knowledge spiral [11], where each transition is analysed and structured to ensure the quality of the information gathered. By analysing each transition of knowledge, e.g. tacit to tacit, the selection or even creation of methods can lead to a more narrow focus, thus an optimised use of resources. By focusing on only the relevant information a more effective and target worthy research process is performed, i.e. optimisation of visits to the user-environment. Blackler's categories of knowledge [2] are applicable to the research process as a more precise description of certain knowledge areas; they are part of the basis that supports the structure of a framework. As mentioned above, the awareness of the types of knowledge desired reflects on the selection and structure of methods of eliciting. The methods can be selected or even created to meet the requirements for gathering a specified type of knowledge. Three knowledge types that are central to consider in development are *procedural knowledge*, *domain knowledge* and *socio-technical knowledge*. Procedural and domain knowledge are significant when a particular working situation is to be understood, whereas socio-technical knowledge is central when a broader perspective is needed. They are not expected to be equally important for all kind of development projects, it depends on the type of organisation, nature of the work, nature of the people etc. Blackler mentions different kind of organisations in which different kinds of knowledge are more dominant and hence more important for the focus of attention.

It is necessary for the researchers and designers to understand the basic of behavioural and perceptive patterns of the user with the purpose of designing the product in the right way. Apart from using knowledge types to understand users, relating to theory on human cognition, cognitive aspects and skills, enables the designers to understand the users' perception of a product and other objects in their every day work situation.

3 METHODOLOGY

The research carried out to elicit the user requirements in such a complex environment as the medico-technical field represents, had to be carefully designed in order to gain deep insight into actual user- and usage experience, in a professional field bound with a series of legal, ethical and practitional limitations. Our research method was therefore constructed to include a series of interviews in companies and case studies in hospitals, which were structured, informed and reflected on by the selection and study of relevant literature to the research. The main elements of our methodology are described in the following.

3.1 Interviews

One of the aims of carrying out this piece of research was to contribute insight and structured input to the actual development of improved medico-technical devices – both in terms of concrete recommendations for device improvements and (most importantly) in terms of methodological organisation for the actual product development methodologies themselves. We therefore based a large focus on understanding how medico-technical companies develop their products today – hereunder how they currently gain and organise their insight into user requirements in the product development process. This research was carried out by interviewing employees of five medico-technical equipment producing companies. The companies interviewed were chosen on the basis of their product lines, which were related to use at hospitals. The participating companies all had more than 300 employees and could hence be classed as large companies, according the EU definition. All interviews took place at the companies and all but one interview included several informants, each of whom represented different professions – but all of whom were employed in either the Marketing or R&D departments of their respective companies. The professions represented in the interviews included nurses, designers, pharmacists and engineers of master and PhD level (mechanic, electro, bio, materials and production). All informants were either project leaders or project team members, but not managers at the strategic level in the company.

3.2 Case Study Research

On the receiving end of the product development chain in the medico-technical field, the users are largely hospital surgeons and to a lesser extent nurses and related staff. It is obviously extremely important to ensure that the voice-of-the-customer is heard when eliciting user requirements. But equally important is to be able to observe the actions-of-the-customer, experiences-of-the-customer and a range of other non-explicit related activities that cannot be captured through merely interviewing the users. We therefore chose to carry out a set of case studies in hospitals. By carefully balancing and structuring a set of inquiry methods, inspired by Yin [17] we carried out two initial case studies in two hospitals in Copenhagen, at the beginning of the research. These case studies – which were constructed from methods such as observations, interviews, discourse analysis and document analysis – were used initially to familiarise us with the hospital environment and the use environment of the medico-technical tools in live operation situations. Later in the research, cases were also used to test the framework developed for the communication of surgeons' experiences.

3.3 Literature study

The literature study carried out for this research prepared the researchers for the topics encountered under the study (e.g. during interviews and observations) and for gaining insight into specific topics related to the problem focus (e.g. regulations in design of medical devices, outcome driven innovation, knowledge types, etc.). The literature study is not the topic of this paper but is documented in detail in [13].

3.4 Limitations in the medico-technical field

We feel it worth mentioning that there are a series of limitations that surround the medico-technical field. Limitations regarding company confidentiality, patient confidentiality, ethical code of conduct, access to main stakeholders (surgeons) under the usage situation (the operation), and the sheer complexity of the field, were very apparent from the very start of the study. These limitations set clear boundaries for the planning, execution and reporting of our research; nevertheless we managed to create a generic and useable set of observations and recommendations for the improvement of product development in the medico-technical field.

4 DIAGNOSIS OF CURRENT PRACTICE: RESULTS FROM INTERVIEWS

From the semi-structured interviews carried out in the five companies it was possible to gain both specific and generic overviews over how the companies elicited user requirements in their product development processes. A summary of the findings from the interview informants follows.

The companies differ in their approach to developing new products. They appear to be skilled in coming up with and handling ideas but experience difficulties in their approach to analysing the use-context of the new product. This is expressed as they mention their difficulty with finding the right methods and right processes for investigating the requirements that users raise for the products. The results of the company analysis show that ongoing work is performed to attempt to optimise the process towards understanding user-environment and thus be able to identify the right requirements and needs.

New approaches have been implemented to identify opportunities and thereby needs e.g. Outcome Driven Innovation (ODI) [16], but the consecutive elicitation of requirements is still problematic as it is unstructured and affected by the preferences of the current project leader. Companies are experienced in methods for research in user environments, but find it difficult assessing which ones are the strongest and/or most appropriate, thus there is a need for a well-structured requirement elicitation process in these complex user environments.

Regulations, complexity and communication by sales departments were anticipated to rank among the reasons for the difficulties in elicitation. The complexity of the environment was not explicitly mentioned as a cause of difficulties (the word was avoided by the researchers during the interviews), but there was a recognition of the difficulty to elicit requirements in medical environments and operating theatres. This was reflected in the constant changes in the companies' requirement elicitation processes. Communication through the sales department is problematic and often insufficient, as it does not convey sufficient or reliable insight back to the designers. Four of the five companies interviewed are intervening in their requirement elicitation processes to include larger and more multidisciplinary teams in their marketing and R&D departments.

In conclusion, the companies use a wide range of methods, primarily for identifying opportunities and field research in the user environment. The companies' follow up on the acquired data is, however, less systematic and reported to be challenging to handle. None of the companies can present an overview or sequence of activities in the elicitation process. A lack of structure for this is expressed as a shortcoming. Due to this, the focus of improvement in the elicitation process was found in all of the five cases to be in the stage of opportunity analysis in their respective Front End of Innovation (FEI) processes [9]. This means any new framework should necessarily focus on the process of capture, representation and communication of user experience in the form of requirements and product features. Project motivation and conceptualisation both are touched upon during the case work, but neither of them is directly targeted by the framework developed. However, conceptualisation cannot be completely separated from the process of eliciting requirements, as ideas for a given issue emerge during the elicitation process. Methods for conceptualisation or project motivation are not addressed directly in the building of the framework.

5 FRAMEWORK

In order to elicit requirements based on user-experience drawn from complex user-environments a framework is constructed. The aim was that the framework should aid the selection of methods and structure the requirement elicitation process. The framework consists of three parts:

- Part I the *knowledge-map* illustrates user-experience in terms of different knowledge types and enables the user of the framework to map methods against the knowledge they target.
- Part II the *methods* are the practical means by which knowledge is captured, represented or communicated.
- Part III the *process-model* drives the process of eliciting requirement through the stages of capture, represent and communicate. The process is inspired by Nonaka's work on organisational learning [10][11].

5.1 Part I: Knowledge Map

Knowledge can be classified, for instance, according to whether it contributes to the ways of doing something (procedural knowledge) or whether it provides the background for making decisions (domain knowledge) [4].

Similarly, it can be either tacit or explicit [14]. These four categories allow the researcher to classify the level of immediate availability and abstraction level of the knowledge to be captured. An additional classification provided by Blackler [2] gives an indication on *where* the knowledge resides and provides a more detailed description of each area in the knowledge-map. Additional knowledge related to values, relations and culture is represented as socio-technical knowledge [3]. User experience is thought to reside in the overlapping areas of these knowledge categories. (see **Figure1**) and is the user's ability to plan and perform a task, make decisions with incomplete or fuzzy information, cope with uncertainty and take action when unexpected events occur.

In order to create an overview of the respective knowledge types and their characteristics, a knowledge map was created. In this map, Blackler's categories or images of knowledge are positioned in the span between tacit and explicit knowledge. These categories or images are called embodied, embrained, encultured, embedded and encoded, as depicted in Figure 1.

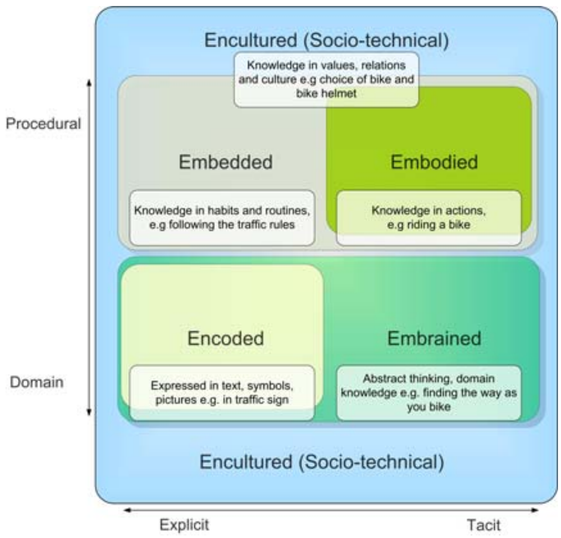

Figure1 Knowledge Map

Embodied knowledge is embedded in the body of an individual by his/her actions and in social systems. Take, for instance, the example of riding a bike. The individual cannot explain exactly how it is done; it has to do with practical experience and physical cues when the bike is at hand. Embodied knowledge is largely tacit knowledge to the individual hence, it is difficult to encode and share with others.

Embrained knowledge is dependent on the individual's conceptual and cognitive ability. It is "intellectual" knowledge. New knowledge is gained from higher level of abstract thinking as understanding complex causations, e.g. specific requirements in product design on basis of insight into a complex user environment.

Encultured knowledge is socially constructed, and deals with the process of achieving shared understanding. It describes the norms and values in social structures and it is therefore dependent on the language and other means of interacting. As encultured knowledge is socially constructed, it can develop or change over time. An example of this is the language in a development team; it will gradually change as the team collects knowledge on the project's specified area. This type of knowledge is acquired through dialogue and mutual experiences, but it also consists of tacit knowledge, which is not formulated.

Embedded knowledge is closely related to encultured knowledge, since embedded knowledge is also created and related to social structures, but it can more easily be analysed from more formalised structures as technical routines, procedures, processes and technologies. This stands in contrast to encultured knowledge, which can only be analysed from social structures between individuals. Hence, embedded knowledge is more explicit than encultured knowledge.

Encoded knowledge is explicit and can be found in literature and other media that can be passed on as codified information e.g. articles, manuals, Internet. Encoded knowledge is de-contextualised and limited to a selected representation of the knowledge presented.

The different types of knowledge categorised and described by Blackler can be used to analyse the situation in which the companies research and gather information as input to their development processes. The understanding of knowledge types and the circumstances that surrounds knowledge is crucial when gathering information. Each of the knowledge types demand to use of specific methods to elicit information and the careful consideration when processing the knowledge to avoid misinterpretations and the loss of important elements in the understanding of the environment being researched.

5.2 Part II: Mapping Methods

The knowledge map was subsequently used in the study to classify knowledge capturing methods, according to their suitability for targeting particular knowledge types, as relevant to the designers. Knowledge capturing will require different methods according to which type of knowledge is to be targeted. A method is to be perceived as a technique for capturing, representing or communicating knowledge. **Figure 2** illustrates how the methods used for capturing in the casework were mapped. Each phase in the requirement elicitation process needs to have a separate 'knowledge-map' so the methods mapped in it are consistent in purpose. Methods are selected from the 'knowledge-map' depending on the kind of knowledge desired.

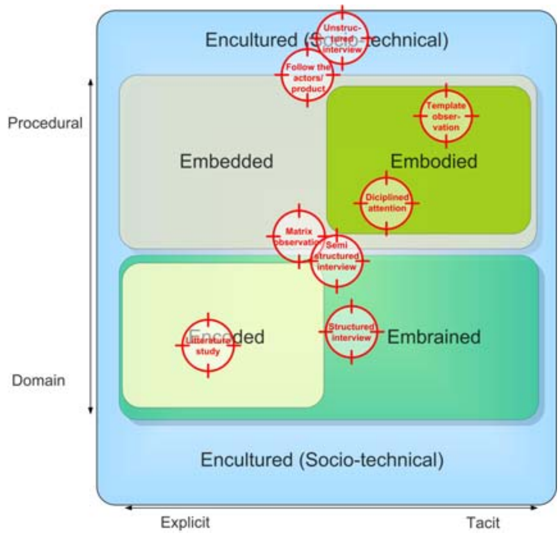

Figure 2 The knowledge map with methods in capture phase

5.3 Part III: Process Model

The final element of the framework is the process model, constructed to inform the requirements elicitation process. The process model is structured into three stages: *capture*, *represent* and *communicate*. These stages are related to the first three stages in Nonaka's the SECI (Socialisation, Externalisation, Combination, Internalisation) model [10][11]. *Capture* is the socialisation stage in which new knowledge is captured from user-environment. *Represent* is the externalisation of findings from tacit to explicit. Finally the findings are combined through a *communication* stage where the recipients of the communication are the developers.

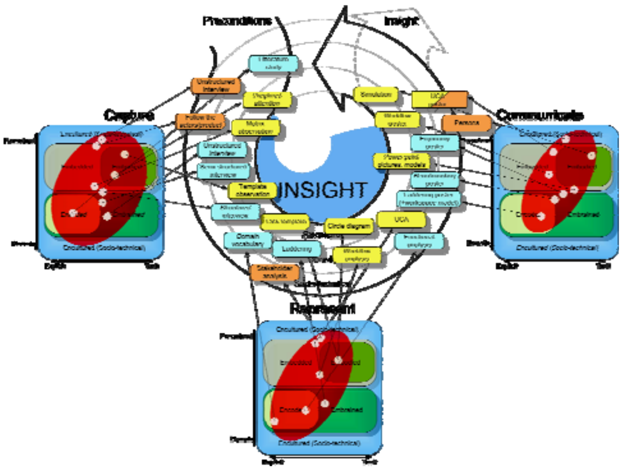

Figure 3 Process Model and examples of knowledge maps

The intention of the process model is that product developers will use the knowledge obtained to articulate requirements and come up with ideas and concepts. The process is iterative and repeats once a concept is ready and becomes convergent as a project progresses. Thus the model is depicted as a circular loop.

The methods selected through use of the 'knowledge-map' are entered into the process and planned in an appropriate sequential order. **Figure 3** illustrates the 'process-model' in combination with the 'knowledge-map'.

6 CASE STUDY

6.1 MIS as a complex environment

The environment in a Minimally Invasive Surgery room has been chosen as a case study as it complies with several characteristics of complex environments. These characteristics are namely time critical decision-making, low tolerance for errors, team collaboration, highly specialised knowledge, highly specialised skills and possible unforeseeable events which can have catastrophic consequences. Furthermore, there is a significant amount of domain and procedural knowledge distributed amongst many actors, it is difficult to gain access to this environment and there are heavy ethical issues in collecting data.

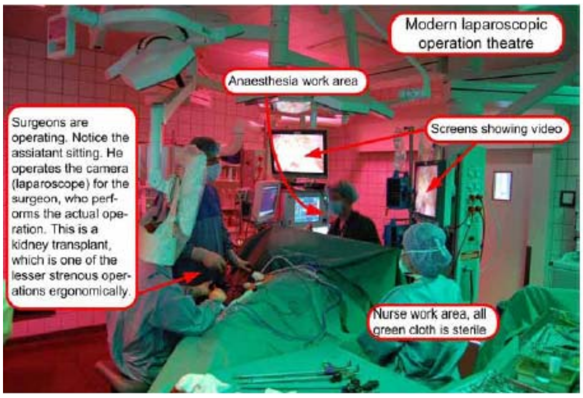

Figure 4 The MIS operating theatre as a complex environment

6.2 Case scope and boundaries

The scope of the case was defined was to increase the safety of the surgeons performing minimally invasive surgery by improving their work environment. An obvious element to improve is to reduce the risk of discomfort and eventual professional injuries caused by poor instrument design (see for example **Figure 5**).

Figure 5 Example of bad ergonomic postures and risk areas to the surgeon

No initial knowledge of minimal invasive surgery

The domain of minimally invasive surgery was relatively new to the researchers, except for knowledge acquired in other concept development projects within the medical field. All insight into the domain of minimally invasive surgery had to be gained from a limited number of visits to the operating theatres. The researchers did not know beforehand what types of knowledge would be the most relevant to a product development project.

To prepare the process of eliciting requirements, preliminary research was conducted in terms of brief visits to operating theatres accompanied by a doctor who explained the setup. After preliminary research, the aim was to make an incremental improvement due to the purpose of evaluating the framework. Knowledge from the preliminary research was also used to select and prepare methods applied in the requirement elicitation process.

Methods not mapped when initiating the process of eliciting requirements

The framework was developed prior to the observations in the case study, but various parts were adjusted as result of the learning process from capturing knowledge from the user-environment. As part of the development of the framework, the methods used were not positioned in the framework before they were applied. The outcome of the methods in terms of knowledge types was predictable based on experience using the methods in other projects. Not all the methods had the predicted outcome and an adjustment to the selection of methods was needed to target specific knowledge, partially due to the limitations and complexity of the user-environment.

6.3 Using the framework

Capturing

Capturing is the most challenging of all phases, as it is necessary to identify which knowledge is relevant to capture as well as which methods are best suited for capturing such knowledge. In this phase, the knowledge map has proved useful in aiding the assessment of relevance of knowledge and the selection of methods. For instance, procedural tacit knowledge is best captured by using templates prepared in advance after a surgical task analysis [15], and then validated after the surgery through semi-structured interviews. Another example is embedded knowledge, e.g. knowledge made explicit by the products' usecues, which is best captured using methods such as follow-the-actor or disciplined attention.

Representing

Finding suitable ways of representing the captured knowledge is of importance as it not only allows communicating it later to the product development team but also allows for the institutionalisation of this knowledge and facilitating its later re-use in other projects. For instance, domain knowledge is best represented using the outcome of laddering, (surgical) work flow analysis and functional analysis, whereas socio-technical knowledge is best represented using Use Cycle Analysis (UCA) [13].

Communicating

Communicating this vast amount of captured knowledge requires significant effort and resources. Some knowledge can be communicated using reports, video clips and posters but some, such as embodied knowledge, requires an empathic approach. To test different methods, a group of novice designers were invited to a workshop where they were given the assignment of redesigning a handle for a laparoscopic grasper. Knowledge was communicated by means of UCA and ergonomics posters, pictures of surgeons and a home made laparoscopic simulator LIS (see **Figure 6** and note the posture of the participants is similar to the posture of the surgeons in **Figure 5**). The use of this simulator was the single most powerful tool to convey the difficulty in operating the laparoscopic instruments and the ergonomic problems associated to it.

Figure 6 Example of designers trying LIS, a laparoscopic surgery simulator

Requirements Generated

The ability to trace back the origin of requirements has been deemed as important in the medical design industry. The requirements generated during the workshop have been recorded and with the help of the process model, we have been able to trace back all the requirements generated to the individual stages, methods used and raw data collected. Of course many new requirements appeared during the concept generation, as concepts impose new conditions that need to be taken into consideration. A roadmap for requirements can be seen in **Figure 7**. Note that most of the requirements come from work flow analysis and from the empathic design exercise done with the simulator. **Table 1** presents a summary of the type, proportion and origin of the requirements generated during the workshop.

Concepts Generated

The quality concepts generated during the workshop were not as important to the research as it was to test whether the type, format and amount of information provided to the participants were adequate to generate relevant requirements. In this paper we only present the final chosen concept that was used in the validation loop with the surgeons at the hospital. The concepts focus on reducing the strain on the surgeons' wrists and elbows and on allowing a higher number of degrees of freedom at the tip of the tool. See **Figure 8** and [13].

Validating with surgeons

The validation was carried out by presenting a surgeon with the requirements generated, together with low resolution functional models and a high resolution mock-up of the handle (See **Figure 8**). Each of the requirements generated was discussed with the surgeon, who in turn explained why they were relevant or irrelevant. 75% of all requirements generated were deemed as relevant by the surgeon interviewed. The irrelevant requirements were explained by the researchers not fully understanding some of the surgical tasks, or because other (better) instruments could be used for the foreseen uses of this instrument.

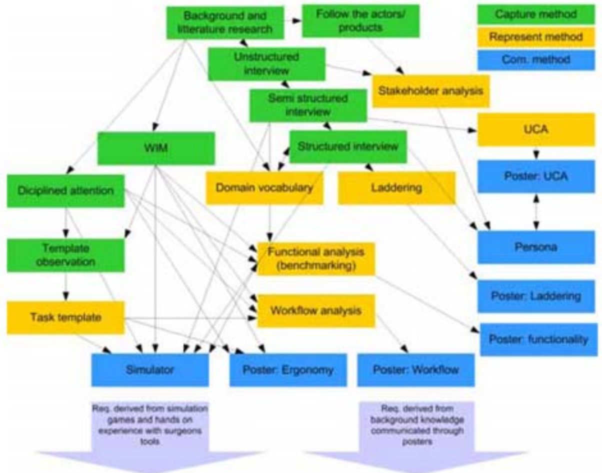

Figure 7 Roadmap of concepts generated

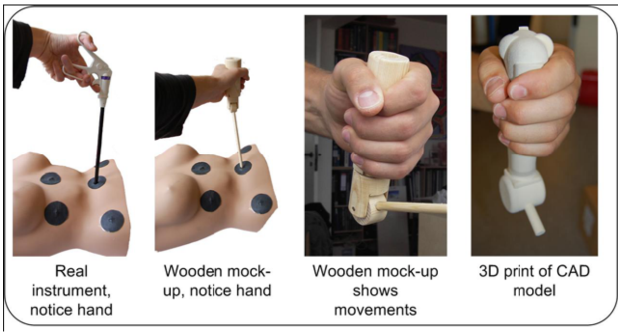

Figure 8 Example of concepts, compared to existing instruments

7 DISCUSSION

7.1 Framework

The framework is established as a synthesis between company findings and theory. Findings from companies have aided to find focus as well as an understanding of the (company) context of the new framework. The theory is the major source for the framework itself; it is constructed on a knowledge-based approach and the idea is that knowledge of the object environment is essentially what is needed, thus elicitation is set up as a process of organisational learning [10][11]. Knowledge-related terms such as *information* and *experience* cannot be disregarded in spite of the knowledge approach, but the intent is that the comprehensive mapping of knowledge creates a picture complete enough for the researcher to map out their methods in the knowledge map.

Origin	Type	Proportion
Simulation	Requirements linked to experience of the participant performing their assignments in the simulation as well as toying with the equipment.	20/42=47.6%
Posters/task	Requirements derived from the background knowledge of the domain and users, presented by posters. Some were explicitly formulated in the design task	13/42= 31%
Other	Requirements linked to ideas discussed by the participants, general considerations of a designer, artifacts placed for inspiration or other things.	9/42=21.4%

Table 1 Origin and proportion of requirements generated during the workshop. A total of 42 requirements were generated

The three parts that form the framework each serve a purpose; the knowledge-map is the "strategic" choice of methods, the process-model implements the learning process and the methods are the practical part specialised for the selected purpose. Complementing these three parts are the preconditions, which are important considerations prior to elicitation.

With regard to complex environments, the idea is that complexity comes from many sources, especially the challenge of understanding different knowledge levels. It must be faced with different kinds of methods that each addresses a relevant subject. The framework is meant to deal with this by mapping out knowledge, identifying relevant focus areas and use methods suitable for the knowledge area to elicit from it.

The analysis of the interviews with companies revealed the most sought-after models or methods are those which address opportunity identification in the Front End of Innovation, and on eliciting requirements in general. Although companies did not explicitly use the phrase *'complex environment'* it was evident to the researchers that the shortcomings in their approach were due to the difficulties in capturing and understanding knowledge in medical environments, legal and ethical aspects and resource limitations.

The framework is a suitable solution to elicit requirements by gaining knowledge. The expected future implications of regulation are only partly handled in the framework. Documentation of the process can be achieved, though exact tracking of requirements is not yet possible. The framework might have an option to expand its usage to support more radical innovation processes.

We argue that the framework has a number of strengths:

- It is well adapted to face diverse challenges in complex environments.
- It gives a structure to an otherwise "fuzzy" process, which is hard to control. The structure includes important phases, each of which contributes to the company in a different way.
- It can help to create a good outline of possible means of eliciting the knowledge necessary.
- It gives an overview of the knowledge levels a user addresses when activities are performed.
- It is easily visualised by means of the knowledge-map and the process-model.
- It is based on theory of organisational learning, combined with experience of companies which can accelerate a company's ability to increase their knowledge pool.

The framework has weaknesses too:

- The abstract notions of knowledge types are an Achilles heel in the framework. They are fundamental for it, but also a weakness as it requires some education to understand and use it.
- The value of the framework is limited as long as the number of methods is not increased and the relations between are not explored.
- The framework has thus far been created and verified within the limited boundaries of the case described in this paper. Our future work will strengthen this situation by applying the framework in participating companies.

It is expected to be a challenge to assess when enough knowledge is gained and it is time to move on from the requirement elicitation process.

7.2 Recommendations about how to best use resources

For companies willing to include the framework into their development processes (or researchers intending to apply the framework), the following recommendations apply when considering your company needs.

If the company has little experience with the use of methods, start by looking into the methods proposed in this project to strengthen parts of the process. Especially 'template observation', graphical representations and simulations have proven effective in this project.

If the company is well acquainted with the use of a diverse palette of methods for elicitation, focus on structure. Improvement of structure by the aid of the framework starts out by using the knowledge-map, making considerations for placement of focus area, mapping the methods on the map, and seeing if it corresponds. Do this for all the phases to identify areas in which the company is unacquainted with good methods. Find appropriate methods to fill in the gaps, and consider how the methods would link together. Use the process-model as a systematic approach, try not to take any short cuts but work through each phase to be acquainted with it. This makes the process more controlled. And please communicate your experiences to the authors!

8 CONCLUSIONS

Although the interviewed companies use already current participatory design and requirements elicitation techniques, there is a lack of understanding of which methods are best suited to capture the different kinds of knowledge, which methods are most fitting to modelling or representing experience and how to transform requirements into product features.

The introduction in this project of a focus on knowledge types and the subsequent mapping of methods and approaches to these, has led to a promising and novel way of eliciting many types of user requirement that would not have been captured through traditional or generic observation techniques.

The knowledge map has been tested and proved to be a useful tool to understand surgical experience, to map the surgeons' knowledge and the contextual aspects of surgical procedures and to select the best capturing, modelling, representing and communicating techniques. Additionally, companies have expressed that the process and knowledge maps can be used as a tool to documenting and communicating the experience and requirements elicitation processes internally to other stakeholders.

The approach to user centred design that was adopted in this project is broader than simply listening to the voice-of-the-customer, and involved a socio-technical approach to practice-oriented research, participatory design and organisational learning.

9 REFERENCES

[1] Beyer, H., & Holtzblatt, K. (1998) Contextual Design: Defining Customer-Centered Systems (S. Card, J. Grudin, M. Linton, J. Nielsen, & T. Skelly, Eds.) San Francisco: Morgan Kaufmann.

[2] Blackler, F. (1995) Knowledge, Knowledge work and Organisations: An overview and interpretation, Organisational studies.

[3] Bruun Jensen, C., Lauritzen, P., Olesen, F. (2007) Introduktion til STS; Hans Reitzes forlag.

[4] Christiaans, H. (1992) Creativity in Design: The role of domain knowledge in designing. Lemma: Utrecht.

[5] Alexander, K.; Clarkson, J.; Bishop, D.; Fox, S. (2002) Good Design Practice for Medical Devices and Equipment: Requirements Capture. Engineering Design Centre. Cambridge University.

[6] Cysneiros, L.M. (2008) Requirements Engineering in the Health Care Domain. In: Proceedings of the IEEE International Conference on Requirements Engineering. IEEE.

[7] Jalote-Parmar, A & Badke-Schaub, P. (2008) Workflow Integration Matrix: a framework to support the development of surgical information systems. Design Studies Volume 29, Issue 4, pp. 315-424.

[8] Kanis, H. (2003) “Research in Design: Situated Individuality versus Summative Analysis”, IEA 2003 (pp. 1-4).

[9] Koen, P.; M.Ajamian, G.; Boyce, S; Clamen, A.; Fisher, E.; Fountoulakis, S.; Johnson, A.; Puri, P.;and Seibert, R. (2002) The PDMA ToolBook 1 for New Product Development in Belliveau, P. Griffin, A. and Somermeyer, S. Eds. Wiley.

[10] Nonaka, I.; Toyama, R. (2003) The Knowledge-creating theory revisited: Knowledge creation an a synergising process. Knowledge Management Research & Practice (2003) 1, 2–10

[11] Nonaka, I.; Takeuchi, H (1995) The Knowledge Creating Company: How Japanese Companies Create the Dynamics of Innovation. Oxford University Press

[12] Nuseibeh, B., & Easterbrook, S. (2000) Requirements Engineering: A Roadmap. In Proceedings of the Conference on The Future of Software Engineering. Limerick. Ireland.

[13] Pedersen, S.M.; Nielsen, T.A. (2008) Eliciting Requirements from a Complex Environment: A framework. M.Sc. Thesis. Department of Management Engineering. Technical University of Denmark.

[14] Polanyi, M. (1966) The Tacit Dimension. Gloucester, MA: Peter Smith, Christensen, Karina S. (2007): 'Perspektiv(er) på knowledge management', Knowledge Management. Børsens ledelseshåndbøger, Børsens Forum A/S.

[15] Sarker, S; Chang, A; Albrani, T.; Vincent, C. (2008) Constructing hierarchical task analysis in surgery. Surg Endosc (2008) 22: 107–111

[16] Strategyn(2008) Outcome Driven innovation (www.strategyn.com) [Accessed 01.01.2008]

[17] Yin, R. (2002) Case Study Research: Design and Methods, Third Edition, Applied Social Research Methods Series, Vol 5 Sage Publications.